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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,814	03/30/2001	Miklos Csore	4175	6646

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THE REILLY INTELLECTUAL PROPERTY LAW FIRM, P.C.
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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,814	CSORE ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-26 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-26, and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 15 June 2006, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-8, 10-26, and 28-31 are currently pending in this application. Claims 9 and 27 have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite "wherein a computer database is provided for storing information" in the preamble. The claim later recites "managing said blood products by preparing a patient identification database". Firstly, it is unclear if these two databases are the same database or two different databases. Secondly, on page 3, line 9, the claim further recites "and storing said compatibility results in said database". Is this information to be sorted in the patient identification database or in the database of the preamble (assuming the two are different databases)? Clarification is requested via clearer claim language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 10-26, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brodheim (Symposium on Computers in the Clinical Laboratory, "Automated Systems in Blood Banking", in Clinics in Laboratory Medicine (1983) Vol. 3, No. 1, pages 111-132), in view of Safwenburg et al. (Vox Sanguinis (1997) Vol. 72, pages 162-168). ***This is a new grounds of rejection based upon Applicant's arguments and amendments to the instant claims.***

The instant claims are drawn to a method and system for managing and tracking blood products.

In regard to claims 1, 10-20, 25, 26, 29, and 30 Brodheim teaches automation of blood banking procedures, including the availability of centralized information pertaining to available blood products from a donor blood bank (page 112, paragraph 1; page 117, paragraph 5). Further, blood products may be requested for transfer to remote facilities (page 120, line 1, page

125, paragraph 4). Brodheim teaches that the blood products are managed such that compatibility testing is performed between patient and donor blood products (page 113, lines 1-4). Antibodies and antigens are compared (page 124, paragraph 2; page 125, paragraphs 1 and 2). All information may be managed such that tracking the blood products is efficient from a centralized database (page 129, paragraph 3). Blood types from patients and donors are assessed in the laboratory system (page 112, paragraph 5). Expiration dates of samples are monitored (page 113, paragraph 4; page 117, paragraph 6)

In regard to claims 2, 7, 21, 22 Brodheim teaches the storing of patient information, such as patient identifying information and the quantity and types of blood components needed (page 112, paragraph 4; page 116, paragraph 6 to page 117, paragraph 1).

In regard to claim 3, Brodheim teaches tracking of blood products so that each product is linked to the donation product from which it was derived (page 126, paragraph 1).

In regard to claims 4 and 31, Brodheim teaches display of the patient identification information (page 114, paragraph 3 (retrieving information through terminals).

In regard to claim 5, Brodheim teaches retrieval of information from remote locations (page 114, paragraph 5).

In regard to claims 6, Brodheim teaches information on crossmatching of patient and donor samples stored in the database and labeled (page 117, paragraph 4).

In regard to claim 8, Brodheim teaches bar coding the samples based on compatibility sampling and other criteria (page 117, 6).

In regard to claims 23 and 24, Brodheim teaches a donation database that stores information on each blood donation for future access, meeting the limitations of claims 23 and 24 (page 116, paragraphs 3-5)

In regard to claim 28, donations reserved are taught at page 116, paragraph 5 (i.e. the database stores information on specific donations)

Brodheim does not specifically teach remote serological cross-matching of a blood specimen and a segment to determine compatibility, as in instant claim 1. However, Safwenberg teaches the ABCD system and procedure for delivery of blood units from a donor to a patient (see Figure 1, page 164). This involves providing an inventory of blood products from donors (page 163, column 1, paragraph 2 and Figure 1 (blood in stock), page 164). Blood products are selected and transferred to the patient (page 163, column 2, paragraph 2). Samples are cross-matched and antibody/antigen testing is performed and verified (page 163, column 1, paragraph 2). Patient specific information is stored, which correlates to blood group information, type components, etc at page 163, column 1, paragraph 2. Tracking is maintained in the computer file and bar coding is used to monitor the blood products (page 163, column 2, paragraph 1 and 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have combined the automated procedure of blood banking taught in Brodheim with another aspect that includes remote serological cross-matching information as taught by Safwenberg. One would have been motivated to combine the two because Brodheim teaches that blood banks are turning to automated systems to alleviate oversight problems (page 111) and that it is integral to establish compatibility between donors and potential recipients (page 111).

Thus, one would have integrated the cross-matching at a test facility to the databases, as taught by Brodheim, with full expectation of success.

NOTE: In arguments regarding 35 USC 102(b), of which the rejections have been withdrawn in view of Applicant's arguments, Applicant states that Brodheim "does not disclose a single database as recited in claim 1".

This is not persuasive. Claim 1 recites a remote patient facility and central blood facility wherein a computer database is provided for storing information. Brodheim teaches a system in which a computer database is provided for storing information. For example, Brodheim teaches a database for storing information about typing to characterize antigens (page 112). The claim does not require that all of the steps are incorporated into one database and therefore, Brodheim teaches all of the embodiments of the instant claims. In fact, the claim 1 includes two different databases, one recited in the preamble and one recited as a patient information database.

Applicant argues that Brodheim makes no reference to transferring blood products to a plurality of remote facilities.

This is not persuasive. Brodheim teaches transfer to remote facilities at page 113, where blood is released from the blood bank and sent to another location (as tracked by a database). Further, at page 125 Brodheim teaches inventory management and release of blood to a patient

The arguments with regard to cross-matching and Brodheim are moot in view of the new grounds of rejections.

Conclusion

No claims are allowed.

The rejections under 35 USC 112, 2nd paragraph have been withdrawn in view of Applicant's amendments to the claims and the telephone conversation with John Reilly on May 31, 2006.

The rejection under 35 USC 102(b) have been withdrawn in view of Applicant's arguments regarding cross-matching.

The outstanding claim objections have been withdrawn in view of the amendments to the claims.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

September 11, 2006
Lori A. Clow, Ph.D.
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER
9/12/06